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SLT FUMICH PROBE GUIDE **510K SUMMARY**

Device Description:

The SLT Fumich Probe Guide geometry consists of PVC tubing with an adjustable sleeve being a 2-pronged fork on the distal end and a silicone connector on the proximal end of this tubing. Total length of this is approximately 4 inches. The distal end configuration is designed to slide onto tissue and stabilize this tissue. Laser fiber is threaded through the lumen of this guide with a probe at the end of the fiber for direct contact with tissue. Therefore, this configuration allows the user to know where the tissue and the probe are making contact and facilitates contact of the probe to tissue.

Equivalency:

The SLT Fumich Probe Guide is designed to be used with the distal end of the SSRH8 handpiece. This hand-piece is inserted through the proximal end of the Fumich Probe Guide; prior to use, a probe can be threaded onto that hand-piece and then withdrawn through the guide so that the guide can be first placed on tissue locating the tissue for contact with the probe. This accessory to the SLT Laser Multidimensional Fiber Delivery System is similar to the CO2 laser arm distal end that incorporates the tissue stabilizer or backstop such as that for the Sharplan 1100 CO2 surgical laser system. CO2 lasers have this guide to facilitate the tissue fiber location for assuring the location of the coagulation and vaporization of tissue.

Conclusion:

The SLT Fumich Probe Guide will be provided as a sterile single use only accessory to the SLT Multidimensional Fiber Delivery System.